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porous structure.

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18 CLAIMS

A tissue scaffold which comprises a matrix comprising a solid or semi solid first phase and, contained within and distributed through the first phase, a second phase which optionally additionally contains cells, and wherein the matrix has a

- 2. A tissue scaffold according to claim 1, wherein the second phase is solid.
- A tissue scaffold according to claim 2, wherein the second phase comprises a solid particulate material contained within and distributed through the first phase.
- 4. A tissue scaffold according to claim 3, wherein the solid particulate material is porous.
- 5. A tissue scaffold according to any one of claims 1 to 4, wherein the first phase or the second phase or both the first phase and the second phase comprises one or more of the polymers selected from  $poly(\alpha-hydroxyacids)$ , polylactic or polyglycolic acids, poly-lactide poly-glycolide copolymers, poly-lactide polyethylene glycol (PEG) copolymers, polyesters, poly (ε-caprolactone), poly (3-hydroxy-butyrate), poly (s-caproic acid), poly (p-dioxanone), poly (propylene fumarate), poly (ortho esters), polyol/diketene acetals addition polymers, polyanhydrides. poly (sebacic anhydride) (PSA), poly (carboxybiscarboxyphenoxyphenoxyhexane) (PCPP). poly [bis(pcarboxyphenoxy) methane] (PCPM), copolymers of SA, CPP and CPM poly (amino acids), poly (pseudo amino acids), polyphosphazenes, derivatives of poly [(dichloro) phosphazene], poly [(organo) phosphazenes] polymers, polyphosphates, polyethylene glycol polypropylene block copolymers, natural polymers, silk, elastin, chitin, chitosan, fibrin, fibrinogen, polysaccharides (including pectins), alginates, collagen, poly (amino acids), peptides, polypeptides or proteins, co-polymers prepared from the monomers of these polymers, random blends of these polymers or mixtures or combinations thereof.

- 6. A tissue scaffold according to claim 5, wherein the polymer is biodegradable.
- A tissue scaffold according to either claim 5 or claim 6, wherein the polymer is crosslinked.
- 8. A tissue scaffold according to any one of claims 5 to 7, wherein the first phase or the second phase or both the first phase and the second phase comprises a polymer and a plasticizer.
- A tissue scaffold according to any one of claims 1 to 8, which additionally contains cells.
- A tissue scaffold according to claim 9, wherein the cells are provided in the second phase.
- 11. A tissue scaffold according to either claim 9 or claim 10, in which the cells are animal cells.
- 12. A tissue scaffold according to claim 11, in which the cells are mammalian cells.
- 13. A tissue scaffold according to claim 11, in which the cells are human cells.
- 14. A tissue scaffold according to any one of claims 11 to 13, in which the cells are bone, osteoprogenitor cells, cardiovascular cells, endothelial cells, cardiomyocytes, pulmonary or other lung cells, gut or intestinal cells, cartilage, muscle, liver, kidney, skin, or specialised cells such as placental, amnionic, chorionic or foetal cells, stem cells, chondrocytes, or reprogrammed cells from other parts of the body such as adipocytes reprogrammed to become cartilage cells.
- 15. A tissue scaffold according to any one of claims 1 to 14, in which the matrix further comprises one or more factors useful for the promotion of tissue growth and development.

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- 16. A tissue scaffold according to ciaim 15, wherein the factors in the matrix comprise epidermal growth factor, platelet derived growth factor, basic fibroblast growth factor, vascular endothelial growth factor, insulin-like growth factor, nerve growth factor, hepatocyte growth factor, transforming growth factors and bone morphogenic proteins, cytokines including interferons, interleukins, monocyte chemotactic protein-1 (MCP-1), oestrogen, testosterone, kinases, chemokinases, glucose or other sugars, amino acids, calcification factors, dopamine, amine-rich oligopeptides, such as heparin binding domains found in adhesion proteins such as fibronectin and laminin, other amines tamoxifen, cis-platin, peptides and certain toxoids.
- 17. A tissue scaffold according to any one of claims 1 to 16, in which the matrix further comprises drugs, hormones, enzymes, antibiotics, nutrients or other therapeutic agents or factors or mixtures thereof in both the first phase and the second phase.
- 18. A tissue scaffold according to any one of claims 1 to 17, in which each of the first phase and the second phase of the matrix comprises different drugs, hormones, enzymes, antibiotics, nutrients or other therapeutic agents or factors or mixtures thereof.
- 19. A process for the production of the tissue scaffold of claim 1, which process comprises the steps:-
  - 1. bringing a first phase into a fluid state;
  - 2. introducing a second phase into the first phase:
  - mixing the first phase and the second phase such that the second phase is contained within and distributed through the first phase; and
  - 4. allowing the first phase to solidify to a solid or semi solid state with the second phase contained within and distributed through the first phase to form a matrix, said matrix also having a porous structure.
- 20. A process according to claim 19, wherein the second phase is a solid particulate material and wherein the first phase, when in the fluid state, is tacky.

- A process according to either claim 19 or claim 20, wherein the first phase and the second phase are in particulate form and wherein the particles of the first phase, when mixed with the second phase, coat the particulate material of the second phase.
- 22. A process according to any one of claims 19 to 21, wherein, in step 4, the first phase is caused to solidify to a solid or semi solid state by the change of a single parameter.
- 23. A process according to claim 22, wherein the change of a single parameter is selected from a change in temperature, a change in pH, the introduction of a crosslinking, setting or gelling agent, the presence/absence of light, ultraviolet or infra-red curing or under anaerobic conditions.
- 24. A process according to any one of claims 19 to 23, wherein the second phase comprises a porous solid particulate material.
- 25. A process according to claim 24, wherein the porous solid particulate material has a porosity of from 10 to 97%.
- 26. A process according to any one of claims 19 to 23, wherein the first phase or the second phase or both the first phase and the second phase comprises a polymer selected from poly( $\alpha$ -hydroxyacids), polylactic or polyglycolic acids, poly-lactide poly-glycolide copolymers, poly-lactide polyethylene glycol (PEG) copolymers, polyesters, poly (a-caprolactone), poly (3-hydroxy-butyrate), poly (s-caproic acid), poly (p-dioxanone), poly (propylene fumarate), poly (ortho esters), polyol/diketene acetals addition polymers, polyanhydrides, poly (sebacic anhydride) (PSA), poly (carboxybiscarboxyphenoxyphenoxyhexane) (PCPP), poly [bis(p-carboxyphenoxy) methane] (PCPM), copolymers of SA, CPP and CPM poly (amino acids), poly (pseudo amino acids), polyphosphazenes, derivatives of poly [(dichloro) phosphazene], poly [(organo) phosphazenes] polymers, polyphosphates, polyethylene glycol polypropylene block copolymers, natural polymers, silk, elastin, chitin, chitosan, fibrin, fibrinogen, polysaccharides (including pectins), alginates, collagen, poly (amino acids), peptides, polypeptides or proteins, co-polymers prepared from the

monomers of these polymers, random blends of these polymers or mixtures or combinations thereof.

- 27. A process according to claim 26, wherein the polymer is biodegradable.
- 28. A process according to either claim 26 or claim 27, wherein the polymer is caused to undergo crosslinking.
- 29. A process according to any one of claims 19 to 28, wherein a plasticizer is added to the first phase or the second phase or to both the first phase and the second phase.
- 30. A process according to any one of claims 19 to 29, wherein cells are incorporated into the second phase.
- 31. A process according to any one of claims 19 to 30, wherein the first phase transforms to a solid or semisolid state at or close to the body temperature of an animal, including human, and wherein, after the mixing step 3., the mixture is introduced into the body of the animal prior to the solidification step 4.
- 32. A process according to claim 19, wherein the first phase comprises a material which in step 4 forms a gel.
- 33. A process according to any one of claims 19 to 32, including an additional step of shaping or partially shaping the matrix before insertion into or onto target tissue.